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Fausto Pinna

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EXAMINER

JACKSON, BRANDON LEE

ART UNIT

PAPER NUMBER

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NOTIFICATION DATE

DELIVERY MODE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### **DETAILED ACTION**

This application is in response to amendments/arguments filed 4/16/2008.  
Currently, claims 41 and 46-64 are pending in the instant application.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 41 and 46-64 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Objections***

Claim 63 is objected to because of the following informalities: "a removable protective film" should be "the removable protective film" or "said removable protective film" because the removable protective film was positively recited in claim 62, from which the claim 63 depends. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 57 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant refers to Fig. 2 in the claim; however, this practice is

not permitted as alternative to spelling out a description of the device. The claim should specifically recite structure(s) to claim the patch.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 62 is rejected under 35 U.S.C. 102(a) as being anticipated by Spyropoulos et al. (WO 02/102425). Spyropoulos discloses a breathable (page 8, lines 12-13) pad (10) comprising a vapor-permeable flexible, porous support (16), a layer of gel (12) applied directly to one surface of the flexible porous support (16), and wherein the pad is configured to allow evaporation of water through the flexible porous support (16). Applicant stated the limitations after the layer of gel are optional; therefore, those limitations following "optionally" have not been considered in the instant rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 41, 48, 52-55, and 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spyropoulos et al. (WO 02/102425) in view of Costa et al. (US Provisional Patent Application 60/418,726). Spyropoulos discloses a breathable (page 8, lines 12-13) pad (10) comprising a vapor-permeable flexible, porous support (16), a layer of gel (12) applied directly to one surface of the flexible porous support (16), wherein the pad is configured to allow evaporation of water through the flexible porous support (16), and medicament (page 6, lines 24-26). The flexible porous support (16) comprises non-woven polyester or polyethylene (page 8, lines 26-28) and has a thickness between 15 and 200 microns (page 8, lines 16-17). Spyropoulos fails to disclose the composition of the hydrogel, the density and weight of the flexible porous support. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the porous support to have a density between 65 and 145 g/dw<sup>3</sup> and a weight between 15 and 200 g/m<sup>2</sup>, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. The optimum range would have been discovered through experimentation to create a

flexible support with ideal weight, density, and transmission rates while remaining comfortable for the user.

Costa teaches a topical hydrogel for wound treatment (abstract) comprising 50 to 77% water (page 4, lines 6-13), 6.5 to 44% dermatologically compatible polymer (page 4, lines 6-13), and 5% volatile substance (page 4, lines 2-4), which is plant oil extracts (page 4, lines 1-13). The volatile substance obviously can be any plant oil extract, because the reference anticipated all plant oil extracts, such as clove (page 4, lines 1-4), *Eucalyptus*, or black pepper. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Spyropoulos device with the composition, as taught by Costa, in order to aid in the healing of the wound. Spyropoulos/Costa discloses all the structural elements and compositions of the claimed invention; therefore the device obviously would be able to accomplish the same intended uses, as well as the method steps would have resulted from the use of the device.

Claims 47 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spyropoulos/Costa as applied to claims 41 and 62 above, and further in view of Spence (US Patent 4,226,232). Spyropoulos/Costa fails to disclose an airtight package. However, Spence teaches a wound dressing (10) contained within an airtight package (14). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Spyropoulos/Costa with the airtight package, as taught by Spence in order to retain the sterility of the pad until use.

Claims 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spyropoulos/Costa as applied to claims 41 and 62 above, and further in view of Shimizu et al. (US Patent 6,306,898). Spyropoulos/Costa fails to disclose the gel comprises sodium alginate or calcium alginate, polyvinyl alcohol or carboxymethylcellulose, and sodium polyacrylate or polyvinyl pyrrolidone. However, Shimizu teaches external skin treatment comprising carboxymethylcellulose, polyvinyl alcohol, sodium alginate, or sodium polyacrylate. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Spyropoulos/Costa gel with carboxymethylcellulose, polyvinyl alcohol, sodium alginate, or sodium polyacrylate, as taught by Shimizu, in order to provide the gel with a stable base material.

Claim 56 rejected under 35 U.S.C. 103(a) as being unpatentable over Spyropoulos/Costa as applied to claim 41 above, and further in view of Lange et al. (US Patent Application Publication 2004/0131660). Spyropoulos/Costa fails to disclose the gel comprises carboxymethyl betaglukan. However, Lange discloses a porous sheet coated in an oil-in-water emulsion, wherein it includes carboxymethyl betaglukan. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Spyropoulos/Costa gel with carboxymethyl betaglukan, as taught by Lange, in order to promote better healing of the wound.

Claims 46 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spyropoulos/Costa as applied to claims 41 and 62 above, and further in view of

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Miranda et al. (US Patent 4,915,950). Spyropoulos/Costa fails to disclose a siliconized polyester removable protective layer. However, Miranda teaches a transdermal patch comprising a removable protective layer made of siliconized polyester (col. 8, lines 49-52). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Spyropoulos/Costa device with a removable protective layer, as taught by Miranda, in order to preserve the adhesive until use of the device.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON JACKSON whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brandon Jackson/  
Examiner, Art Unit 3772

BLJ

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772